Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research

In accordance with the NIH guidelines on the inclusion of women and minorities as subjects in clinical research, the Cancer Therapy Evaluation Program; Division of Cancer Treatment, Diagnosis, and Centers; NCI requires that all protocols, including those submitted by the NCI Cooperative Groups, contain a standard section devoted to women and minorities. In this section, the investigators are to consider aspects of the diseases (such as response to therapy, survival, etc.) with respect to sex and race and review past studies for relevant information.

The NIH policy was implemented in accordance with section 492B of the Public Health Service Act under Public Law 103-43. The policy states that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. All NIH-supported biomedical and behavioral research involving human subjects is defined as clinical research. This policy applies to research subjects of all ages.

Phase I and Phase II clinical studies must be designed to include women and minorities but are not required to be designed to measure differences of intervention effects. For these studies, the systematic inclusion and reporting of information on women and minorities will contribute to an increase in the scientific base of knowledge about them and will aid investigators in planning Phase III clinical trials.

When a Phase III clinical trial is proposed, evidence must be reviewed to show whether clinically important gender, race or ethnicity differences in the intervention effect are to be expected. This evidence may include, but is not limited to, data derived from: prior animal studies, clinical observations, metabolic and genetic research, recreation studies, pharmacology, natural history, epidemiology and other relevant studies.

Investigators should consider the following circumstances when planning a Phase III clinical trial:

If prior data strongly indicate that the intervention will show significant clinical or public health differences among gender, racial, and/or ethnic subgroups, then the primary question(s) to be addressed and the design of that proposed Phase III trial must specifically accommodate these differences. For example, if men and women are thought to respond differently to an intervention, the Phase III trial must be designed to answer two separate primary questions, one for men and the other for women, with adequate sample size for each.

If prior data strongly support no significant clinical or public health differences among subgroups from the intervention, then gender, race and/or ethnicity will not be required as subject selection criteria. However, the inclusion of gender, racial and/or ethnic subgroups is still strongly encouraged.

If prior data neither strongly support nor negate the existence of significant clinical or public health differences among subgroups, then the Phase III trial must include sufficient and appropriate gender, racial and/or ethnic subgroups, so that valid analysis of the intervention effect on subgroups can be performed. However, the trial will not be required to provide high statistical power for each subgroup.

In order to comply with the NIH policy, all protocols submitted to CTEP for Protocol Review Committee (PRC) review must contain a separate section, "Inclusion of Women and Minorities," which describes the inclusion of women and members of minority groups appropriate to the scientific objectives of the study. In the protocol, the investigators must describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. A description of the proposed outreach programs for recruiting women and minorities as participants should also be included. Protocols that do not contain this section will be returned without PRC review.